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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

BRAINTREE LABORATORIES, INC.,	)	
Plaintiff,	)	
	)	
v.	)	<b>Civil Action No 3:11-cv-01341</b>
	)	<b>(PGS) (LHG)</b>
NOVEL LABORATORIES, INC.,	)	
Defendant.	)	
	)	

**PLAINTIFF BRAINTREE LABORATORIES, INC.'S OPPOSITION TO  
DEFENDANT NOVEL LABORATORIES, INC.'S MOTION *IN LIMINE* (NO. 1) TO  
LIMIT DR. CLEVELAND, DR. FORDTRAN, AND MR. MCGOWAN TO TESTIMONY  
BASED ON FED. R. EVID. 602 PERSONAL KNOWLEDGE AND PRECLUDE  
UNDISCLOSED OPINION TESTIMONY**

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## **I. INTRODUCTION**

In its motion *in limine* No. 1, Dkt. No. 230, Novel Laboratories, Inc. (“Novel”) attempts to preclude relevant, admissible testimony by Dr. John Fordtran and Dr. Mark Cleveland, the inventors of the patent-in-suit, and by Mr. John McGowan, a supervisor of clinical trials for the product at issue, SUPREP® Bowel Prep Kit (“SUPREP”).

Novel’s position that Dr. Fordtran, Dr. Cleveland, and Mr. McGowan cannot provide lay opinion testimony misstates the law and ignores these witnesses’ personal, particularized knowledge regarding SUPREP and its development, and the gastroenterology field. Excluding this testimony would deprive the Court of important and helpful information relevant to the issues in this case. Such opinion testimony, when based on personalized knowledge, is admissible under Fed. R. Evid. 701 and Third Circuit controlling precedent.

For these reasons, Novel’s motion *in limine* to limit the testimony of Dr. Fordtran, Dr. Cleveland, and Mr. McGowan lacks merit and should be denied.

## **II. ARGUMENT**

### **A. Legal Standard**

Generally speaking, a lay witness may not provide opinion testimony based on scientific, technical, or other specialized knowledge. Fed. R. Evid. 701(c); *see, e.g., Hirst v. Inverness Hotel Corp.*, 544 F.3d 221, 227 (3d Cir. 2008).<sup>1</sup>

But significantly, lay testimony of a technical or scientific nature that is based on particularized or personalized knowledge is admissible under the “personalized knowledge

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<sup>1</sup> The Federal Circuit reviews a district court’s evidentiary rulings under the law of the regional circuit. *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1331 (Fed. Cir. 2010).

exception.” *See Donlin v. Philips Lighting N. Am. Corp.*, 581 F.3d 73, 81-83 (3d Cir. 2009); *see also Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1175 (3d Cir. 1993) (allowing a company’s founder and owner to opine regarding his lost future profits and harm to the value of his business); *Maxfield v. Sinclair Int’l*, 766 F.2d 788, 797 (3d Cir. 1985). As explained below, this principle is well-established in the Third Circuit and elsewhere. It is widely applied in patent cases so that lay technical testimony may be received for the fact-finder’s benefit. *See, e.g., Verizon*, 602 F.3d at 1339-40 (allowing lay testimony from inventors regarding their patent, based on their personal knowledge); *The Braun Corp. v. Maxon Lift Corp.*, 282 F. Supp. 2d 931, 933-34 (N.D. Ind. 2003), *aff’d sub nom. Braun Corp. v. Maxon Lift Corp.*, 97 F. App’x 335 (Fed. Cir. 2004) (per curiam) (allowing lay testimony of patent inventor regarding the structure and function of the patented invention, the accused device, and other technical issues, where the inventor had been involved in that technical field for sixteen years, possessed specialized knowledge of the technology, and had personally examined and studied the accused device).

Courts and the Advisory Committee Notes make clear that an exception to Fed. R. Evid. Rule 701(c) applies for lay testimony based on personalized or particularized knowledge. *See* Fed. R. Evid. 701, Advisory Committee Notes (noting approvingly the practice of “most courts” that lay opinion testimony based on particularized knowledge “is admitted not because of experience, training or specialized knowledge within the realm of an expert, but because of the particularized knowledge that the witness has by virtue of his or her position in the business. The amendment [i.e., Rule 701(c)] does not purport to change this analysis.”). The Third Circuit has clearly adopted this approach for its District Courts: “When a lay witness has particularized knowledge by virtue of her experience, she may testify—even if the subject matter is specialized

or technical—because the testimony is based upon the layperson’s personal knowledge rather than on specialized knowledge within the scope of Rule 702.” *Donlin*, 581 F.3d at 81.

Courts often allow lay testimony of inventors or engineers regarding technical aspects of an invention or pieces of prior art when such testimony is based on personalized knowledge. *See, e.g., Corning Inc. v. SRU Biosystems*, CIV.A. 03-633 JJF, 2005 WL 2465900 at \*7-8 (D. Del. Oct. 5, 2005) (allowing lay testimony of defendant’s chief technical officer as to its technology based on his own personal perception); *Fresenius Med. Care Holdings, Inc. v. Baxter Int’l, Inc.*, C 03-1431 SBA, 2006 WL 1330002 at \*3 (N.D. Cal. May 15, 2006) (allowing lead engineer in development of heart lung machine to testify as a lay witness regarding the machine and the way it operates, based on personal knowledge); *Braun*, 282 F. Supp. 2d at 933-34.

Inventors are often the most helpful type of witness to aid the court in understanding the invention, the patent, and the problems faced in the prior art. *See Verizon*, 602 F.3d at 1339-40 (citing *Voice Tech. Grp., Inc. v. VMC Sys., Inc.*, 164 F.3d 605, 615-16 (Fed. Cir. 1999)); *Voice Tech*, 164 F.3d at 615-616 (noting “the large body of precedent that recognizes the value of the inventor’s testimony,” and stating, “Patents are written not for laymen, but for and by persons experienced in the field of the invention. An inventor is a competent witness to explain the invention and what was intended to be conveyed by the specification and covered by the claims. The testimony of the inventor may also provide background information, including explanation of the problems that existed at the time the invention was made and the inventor’s solution to these problems.”) (citations omitted); *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1580 (Fed. Cir. 1996) (inventor’s testimony considered as “enlarging [Federal Circuit’s] understanding of the technology and the usage of the disputed terms”).

**B. Dr. Fordtran Should be Permitted to Testify as to the Invention and the Field of the Invention Based on His Extensive Personalized Knowledge**

Dr. Fordtran, an inventor on the '149 patent, is the Director of the Gastrointestinal Analytical Laboratory at Baylor University Medical Center. The evidence will show Dr. Fordtran's extensive knowledge and experience in the gastroenterology field, as described in brief here. Dr. Fordtran is the former Chief of Internal Medicine at Baylor University Medical Center, serving in that role from 1979 to 1997. He also served as president of the Baylor Research Institute from 1991 to 1999. Dr. Fordtran has practiced in gastroenterology for 51 years and is widely considered a leading figure in the field, as Novel's own expert admitted. *See* Supplemental Declaration of Anna E. Lumelsky in Support of Braintree's Oppositions to Novel's Motions in Limine and Related Motions ("Supp. Lumelsky Decl."), Ex. 36, Goldfarb 3/7/12 Tr., at 95:3-5 ("[Dr. Fordtran is] one of the leading gastrointestinal physiologists.").

Dr. Fordtran has published widely on gastroenterology topics, and was a long-time editor of a gastroenterology textbook still considered a gold standard in the field, Sleisenger and Fordtran's *Gastrointestinal and Liver Disease*. Dr. Fordtran was president of The American Society of Clinical Investigation from 1976 to 1977. He served as the editor-and-chief of *Gastroenterology* from 1977 to 1981. In 1984, he was the recipient of the King Faisal International Prize in Medicine for his work on diarrheal diseases; in 1991 he received a National Institute of Health Merit Award. In addition to developing the SUPREP product with Braintree,

Dr. Fordtran participated in the development of other key colon cleansing products on the market today, such as GoLytely and NuLytely.<sup>2</sup>

The *Braun* case is cited above to support permitting inventor testimony regarding the invention and prior art. In *Braun*, the inventor of a wheelchair lift was permitted to provide lay opinion testimony regarding the structure and function of his patented invention, the accused device, and other technical issues. *Braun*, 282 F. Supp. 2d at 933-34. The inventor had been in the field of wheelchair lifts for 16 years and possessed personalized knowledge of the technology, based on having invented it, and had personally studied the accused device. The court therefore allowed his opinion testimony, relying on a Seventh Circuit rule similar to the Third Circuit's personalized knowledge exception, because the testimony was "rationally based on his personal perception." *See id.*

This case presents the same situation. Dr. Fordtran possesses extensive personalized knowledge about matters such as SUPREP, its development and its administration to patients, the gastroenterology field and its history, and the prior art. The Court should allow Dr. Fordtran to present lay opinion testimony under Rule 701 regarding topics of this kind. *See Donlin*, 581 F.3d at 81-83; *Verizon*, 602 F.3d at 1339-40; *Braun*, 282 F. Supp. 2d at 933-34.

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<sup>2</sup> Some of Dr. Fordtran's other contributions in the gastroenterology field include: development of methods to study intestinal absorption and secretion; the discovery of the pathogenesis of diarrhea; the mechanism of absorption of calcium, phosphorus, and magnesium by the human intestine *in vivo*; the effect of reducing gastric acidity on healing of duodenal ulcers; the stimulatory effect of glucose on water and sodium absorption by the human intestine; the discovery of microscopic colitis as a cause of chronic diarrhea; the elucidation of the mechanism of diarrhea in patients with congenital alkalosis; the discovery of cholecystokinin deficiency as the cause of malabsorption in patients with Autoimmune Polyglandular Syndrome; and the effects of cystic fibrosis mutations on intestinal absorption and secretion of water and electrolytes.



**C. Dr. Cleveland Should be Permitted to Testify as to the Invention and the Field of the Invention, as Well as the SUPREP Clinical Trials, Based on His Extensive Personalized Knowledge**

Dr. Cleveland, an inventor on the '149 patent, is the Chief Scientist and the Senior Vice President of Research and Development and Regulatory Affairs for Plaintiff Braintree Laboratories, Inc. ("Braintree"). The evidence will show Dr. Cleveland's extensive knowledge and experience in the gastroenterology field. He holds a Ph.D. in biology from Columbia University, and has worked in the field of gastroenterology for over 25 years. Dr. Cleveland has been a listed author on over thirty peer-reviewed publications or abstracts in the gastroenterology field. At Braintree, Dr. Cleveland's duties include responsibility for clinical studies and clinical development, as well as development of new drugs. He has worked on the development of a number of gastroenterology drugs in addition to SUPREP. Dr. Cleveland participated and consulted with others in the development of clinical trials for SUPREP, and has personal knowledge about many facets of those clinical trials.

Under Rule 701, Dr. Cleveland should be permitted to testify regarding matters such as the invention of the '149 patent, SUPREP and its administration to patients, the SUPREP clinical trials, the gastroenterology field and its history, and the prior art, based on his personal experience and knowledge. *See Donlin*, 581 F.3d at 81-83; *Verizon*, 602 F.3d at 1339-40; *Braun*, 282 F. Supp. 2d at 933-34.

**D. Mr. McGowan Should be Permitted to Testify as to the SUPREP Clinical Trials.**

Mr. McGowan is the Director of Clinical Research at Braintree and has managed a number of SUPREP clinical trials on Braintree's behalf. The evidence will show that Mr.

McGowan has extensive personal knowledge as to how those clinical trials were run, and how patients proceeded through the trials. Mr. McGowan has been named as an author on over ten publications or abstracts in the field. Mr. McGowan should be permitted to testify under Rule 701, as interpreted by the Third Circuit, on those and related topics. *See Donlin*, 581 F.3d at 81-83; *Verizon*, 602 F.3d at 1339-40; *Braun*, 282 F. Supp. 2d at 933-34.

### **III. CONCLUSION**

For all the foregoing reasons, Novel's Motion *In Limine* (No. 1) to Limit Dr. Cleveland, Dr. Fordtran, and Mr. McGowan to Testimony Based on Fed. R. Evid. 602 Personal Knowledge and Preclude Undisclosed Opinion Testimony should be denied.

Dated: January 25, 2013

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